

6/10/03

10/534567

JC20 Rec'd PCT/PTO 12 MAY 2005

1

Accessories for Removing Bone Material and Method for Making

This invention relates to instruments or ancillaries used to remove bones for hip or knee prosthetic surgery and in particular to a rasp for fitting a hip prosthesis and to a cutting unit for fitting a knee prosthesis. This invention also relates to a surgeon's ancillary kit, notably for fitting a hip prosthesis comprising a rasp according to the invention and/or for fitting a knee prosthesis comprising a cutting unit according to the invention.

Rasps, cutting units and other ancillaries for removing bones are well-known in the field. These ancillaries must be hard enough and sufficiently resistant to wear to be able to attack bone and withstand the heavy pressures resulting from the action of a blade with which they cooperate on bone. To date, metals have always been used, which are sufficiently resistant to wear to attack the bone. What is more, they can be reused after re-sterilisation in the autoclave.

However, these ancillaries are expensive to produce due to the material used and the manufacturing method (machining). In addition, for reasons of patient safety, it is not desirable for a rasp or a cutting unit of this kind to be reused a second time by a surgeon after he has himself carried out further sterilisation, particularly because of the risk associated with infections such as Kreuzfeld Jakob disease.

The aim of the invention is to overcome these disadvantages by offering an ancillary for removing bone, for surgery to fit a prosthesis, notably a rasp for fitting a hip prosthesis and/or a cutting unit for fitting a knee prosthesis, which may be simpler to manufacture, less expensive and better suited to producing single-use ancillaries.

From a preliminary view of the invention, the ancillary device is as defined in Claim 1.

When the ancillary is thus heated in an autoclave for example, to try and "re-sterilise" it at a Ti temperature of 137° for example, the metal inserts

irreversibly come away from the body and the ancillary can no longer be used. We can therefore be sure that a new, well-sterilised ancillary will have to be used for a future operation.

By making these ancillaries largely in plastic, the manufacturing process is greatly facilitated (an injection moulding process is now possible) and the cost of the material is reduced. It was thought until now that plastic was not a suitable material for manufacturing these ancillaries, both for reasons of hardness and because it was thought preferable to be able to reuse the ancillary. However, as the plastic used is hard enough, it will be suitable for removing bone and withstanding the pressures associated with the action of a blade on the bone. In addition, by producing the ancillary in plastic, there are greater capacities for manufacturing a single-use, so-called "disposable" ancillary.

As a result of an improvement to the invention, the hardness of the plastic is chosen close to the bone hardness, for example between 5 and 30% higher.

By producing the rasp or cutting unit in this material therefore, we make sure that the ancillary can only be used for a single operation since the material rapidly wears out during the operation to the extent that the ancillary has deteriorated too much by the end of the operation to be able to be reused for another operation.

As a result of an improvement to the invention, the plastic is chosen so that it deteriorates at or above a T_i temperature between 50°C and 200°C, preferably between 70°C and 150°C, specifically at or above a temperature equal to 137°C. We can then be sure that if the surgeon carries out sterilisation by autoclave, notably sterilisation at or below 137°C to ensure that all the prions are fully removed, he will see his cutting unit or rasp deteriorating and will no longer be able to use them.

The initial sterilisation is actually carried out by exposure to γ or β rays. It can only be done once. A second exposure actually degrades the plastic

due to the development of free radicals. The only way until now, therefore, of re-sterilising after initial use was to put the item through an autoclave. As a result of this improvement, this is no longer possible since the ancillary in the autoclave deteriorates and self-destructs. The ancillary can thus no longer be reused legally, although the surgeon can always reuse the ancillary without re-sterilising, but at is his own professional risk, of course.

According to a favourite production method, the plastic is a thermoplastic material, notably a polyvinyl, polyolefin, polyamide or similar material and it deteriorates in particular due to softening.

These materials are structurally not very solid. Nevertheless, they are perfectly well suited for use as a rasp or cutting unit for removing bone, which on the face of it may seem surprising, since one could expect that a rasp or a cutting unit would be produced in a material that has a certain hardness and a certain stress resistance. It transpires, however, that this rasp or cutting unit, which is made at least in part of a thermoplastic material, is perfectly well suited for use. In addition, since the thermoplastic material deteriorates due to softening at 137°C, and even at a temperature below 137°C, we can be certain that the surgeon will not be able to reuse these ancillaries. Finally, as they are largely plastic, they are inexpensive and can therefore be produced on a large scale and disposed of without involving very high running costs.

The aim of this invention is also a surgeon's kit for fitting prostheses, notably hip or knee prostheses, comprising a rasp according to the invention and other ancillaries also in plastic, or a kit comprising a cutting unit according to the invention and one or more other ancillaries also in plastic, the kit being vacuum packed or packed in a sterile atmosphere.

As a result of an improvement to the invention, the ancillary comprises at least one insert in an appreciably harder material than the plastic, metal for example, the insert being at least partly embedded in the plastic and in direct contact with the plastic.

When the plastic, for example, thus softens (as in the case of

thermoplastic) or deteriorates due to decomposition (thermosetting plastic), contact with the insert is broken and the latter can notably break away from the body of the ancillary or assume a non-operational position and the ancillary becomes unusable.

5 As a result of an improvement to the invention, the ancillary comprises one part in a shape memory material harder than the plastic, the shape memory material taking an initial shape above a given T_i temperature, and a second shape below this given T_i temperature, the initial shape being such that when the temperature exceeds T_i and the material takes on this initial
10 shape by itself, the ancillary is then at least partly destroyed.

Improvements are defined in Claims 2 to 8.

The aim of this invention is also a process according to Claim 10.

Figure 1 shows a rasp according to the invention for cutting a bone to fit a hip prosthetic.

15 Figure 2 shows a cutting unit for cutting a bone of the femur or tibia.

Figure 3 shows a kit according to the invention.

Figure 4 shows an alternative to the unit in Figure 2.

Figure 5 shows an alternative to the rasp in Figure 1.

Figure 6 shows an acetabulum drill according to the invention.

20 Figure 1 shows a rasp 1 for a hip prosthesis. It consists of a curved, cylindrical grab handle 2 and of a part 3 of a rasp spiked with protrusions for rubbing the bone to reduce it to powder.

Rasp part 3 is locked at one end of handle 2 by a locking system.

25 Rasp part 3 is made of plastic, notably low or high-density polyethylene (LDPE, HDPE), polypropylene, polyacetal, PVC, etc.

LDPE softens at 104°C and melts at $108\text{-}120^{\circ}\text{C}$, its Shore D hardness being 45-55.

The HDPE softens at $123\text{-}127^{\circ}\text{C}$ and melts at $125\text{-}135^{\circ}\text{C}$, its Shore D hardness being equal to 65-70.

30 PP softens at 149°C and melts at 170°C , at a Shore D hardness of 80.

Handle 2 is made of plastic, for example HDPE.

According to another form of construction shown in the Figure, the protrusions of rasp part 3 are formed by inserts 4 in a harder material, notably metal, which protrude from the plastic, being largely embedded in it.

5 To form rasp 3, a cast is taken by pouring or injection into a mould, inserts 4 being positioned prior to injection in the position they are required to have in the final volume of plastic, then the plastic is poured into the mould and left to cool to produce the final rasp.

10 The inserts also increase the rasp's rigidity. When the rasp is placed in an autoclave for further sterilisation, the plastic softens above the T_g and the inserts come away from the plastic. The rasp can no longer be used. If the rasp has no inserts (the protrusions are made of plastic that is harder than the bone), the rasp is also unusable, the protrusions tending to disappear when the plastic softens.

15 According to another form of the invention, rasp 3 is formed by pouring or injecting the plastic, at least partly, and preferably completely, coating a rod 5 in a harder material, notably a shape memory metal. Before pouring the plastic, the rod is heated to a high temperature (above T_g , which is lower than 137°) and assigned a given shape, bent back into a U for example, so that
20 when rod 5 changes shape to take the given shape in question, it breaks its surrounding material, notably a plastic, which is softer, and the rasp is unusable.

Figure 2 shows a cutting unit 6 for a knee prosthesis. This unit 6 consists of a box-shaped body 7 drilled with two holes 8 for fixing by screw to the bone to be cut and comprises two horizontal slots 9 and two sloping slots
25 11, through which cutting blades can be inserted to resection bones for installing the prosthesis, slots 9 and/or 11 being chosen according to the angle of attack of the cut required.

The cutting unit is made of plastic, notably LDPE, HDPE, PP or similar.

30 It is formed by injection moulding. Metal inserts with or without shape

memory and at least partly embedded in the plastic mass can be used in the same way as for the rasp described above. As can be seen in Figure 4, metal inserts 10 in the form of flexes are arranged on both sides of the openings of slots 9 and 11 to support the blades inserted into the slots during their cutting action on the bone.

Figure 3 shows a tray vacuum-packed with a plastic film sealed at the edges of the tray. Several disposable ancillaries are packed in this tray, some or preferably all of which are partly or entirely made of one or more materials that deteriorate above a Ti temperature between 50°C and 200°C, preferably between 70°C and 150°C and specifically at or above 137°C.

Bone hardness depends on the application, the patient and notably on his or her age. An appropriate plastic will be chosen according to the end use of each ancillary and to whether it is used, for example, to attack the (softer) spongy or (harder) cortical bone.

Figure 6 shows a rasp for acetabulum or drill 20 with acetabulum.

Drill 20 consists of a rod 21 and a hemispherical head 22. Metal blades 23 are embedded in the plastic mass of head 22 and protrude from it as ribs for attacking the bone. Ribs 23 in plastic that is harder than the bone can also be formed in place of the blades by pouring into a suitable mould, that is, one with grooves corresponding to the ribs.